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FAX: (212) 208-6819
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TO : Commissioner for Patents
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FROM : Oleg F. Kaplun, Esq. of Fay Kaplun & Marcin, LLP

DATE : April 11, 2007

SUBJECT : U.S. Patent Appln. Serial No. 09/838,618
for *Catheter Slit Valves*
Inventor(s): Haarala et al.
Our Ref.: 10123/01101

NUMBER OF PAGES INCLUDING COVER: 26

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Attorney Docket No. 10123/01101 (00-0010)

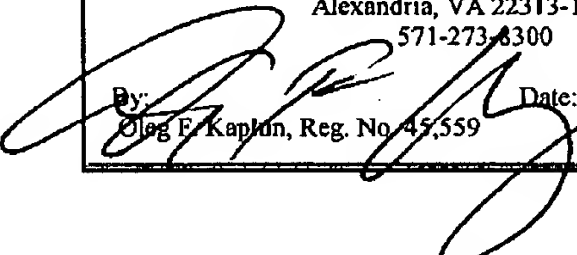
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Haarala et al.
Serial No. : 09/838,618
Filed : April 19, 2001
For : Catheter Slit Valves
Group Art Unit : 3753
Examiner : Eric S. Keasel
Confirmation No. : 3578

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By:  Date: April 11, 2007
Oleg F. Kaplun, Reg. No. 45,559

TRANSMITTAL

In support of the Notice of Appeal filed February 12, 2007, transmitted herewith please an Appeal Brief for filing in the above-identified application. Please charge the Credit card of Fay Kaplun & Marcin, LLP in the amount of \$500.00 (PTO Form 2038 is enclosed herewith). The Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492** for additional required fees. A copy of the paper is enclosed for that purpose.

Respectfully submitted,

Dated: April 11, 2007


By:
Oleg F. Kaplun, Reg. (45, 559)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, NY 10038
Tel: (212) 619-6000
Fax: (212) 619-0276

Attorney Docket No. 10123/01101 (00-0010)

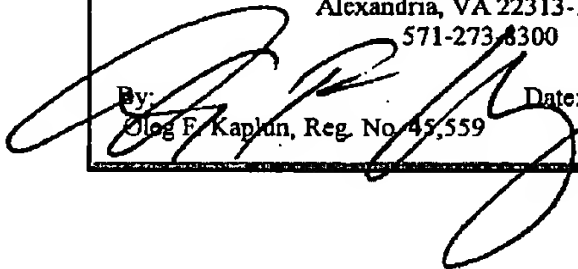
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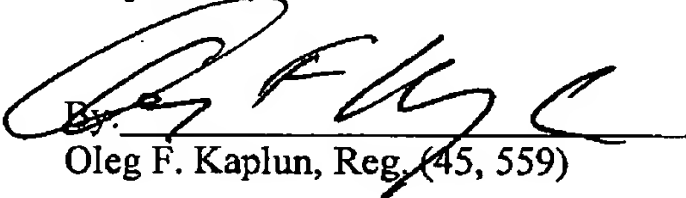
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By: Oleg F. Kaplun, Reg. (45, 559)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, NY 10038
Tel: (212) 619-6000
Fax: (212) 619-0276

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PATENT

Attorney Docket No.: 10123 - 01101

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:

Haarala et al.

Serial No.: 09/838,618

Filed: April 19, 2001

For: CATHETER SLIT VALVES

Confirmation No.: 3578

Group Art Unit: 3753

Examiner: Eric Keasel

Board of Patent Appeals and Interferences

Mail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed February 13, 2007, and pursuant to 37 C.F.R. § 41.37, Appellants present their appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 43 - 46 and 61 in the final Office Action dated November 14, 2006. The appealed claims are set forth in the attached Claims Appendix.

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1. Real Party in Interest

This application is assigned to Scimed Life Systems, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected by, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 43 - 46 and 61 stand rejected in the Final Office Action. The final rejection of claims 43 - 46 is being appealed. Claims 1 - 42 and 47 - 60 have been withdrawn from consideration.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

The present invention, as recited in independent claim 43, is directed toward a medical device 368 comprising an elongate catheter 370 including an external surface 376 and at least one internal surface 374 defining an internal lumen 378 that extends longitudinally along at least a portion of the elongate catheter 376. *Specification*, p. 22, ll. 6-10, Fig. 30A. A compound slit 371 extends from a generally hemispherical portion 373 of the external surface 376 to the at

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least one internal surface 374 and into communication with the internal lumen 378.

Specification, p. 22, ll. 10-13, Fig. 30A-B. The compound slit 371 is biased toward a closed position and opens in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter. *Specification*, p. 21, ll. 22-24, Fig. 30B.

6. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 43 - 44 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,752,970 to Yoon.
- II. Whether claims 43 - 44 and 61 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 3,303,847 to Eaton.
- III. Whether claims 43 - 44, 46 and 61 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 2,063,424 to Ferguson.
- IV. Whether claims 43 - 44 and 46 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 3,718,140 to Yamauchi.
- V. Whether claim 45 is unpatentable under 35 U.S.C. § 103(a) as obvious over Eaton in view of U.S. Patent No. 5,798,018 to Engelson et al. ("Engelson").
- VI. Whether claim 45 is unpatentable under 35 U.S.C. § 103(a) as obvious over Yoon in view of Engelson.

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7. ArgumentI. The Rejection of Claims 43 - 44 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 5,752,970 to Yoon Should be Reversed.A. The Examiner's Rejection

In the Final Office Action, claims 43 - 44 were rejected under 35 U.S.C. 102(b) as anticipated by Yoon. *11/14/06 Office Action*, p. 2.

Yoon purports to describe a cannula 20 for insertion through an anatomical cavity wall including a tubular body 22 with a valve 26 at a proximal end thereof which opens *only* when a trocar 36 is thrust therethrough. *Yoon*, col. 4, ll. 18-20. The valve 26 includes four flaps (valve members) 28-34 biased toward a closed position "when no instrument is passed through the cannula." *Id.*, col. 4, ll. 1-3. The flaps 28-34 open outwardly *only* when the trocar 36 is pushed therethrough. *Id.*, col. 4, ll. 27-32. The valve of Yoon prevents fluid from passing through the cannula 20 at all times (*i.e.*, the valve of Yoon seals tight when no trocar 36 is inserted through the cannula 20 and seals around an outer surface of any trocar 36 inserted therethrough).

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B. Yoon Does Not Disclose a Compound Slit Opening
in Response to a Difference Between a Fluid
Pressure Within the Lumen and a Fluid Pressure
Outside the Catheter as Recited in Claim 43.

Claim 43 recites a device comprising “an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter” and “a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, *the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.*”

In the final rejection, the Examiner stated that the “slit of Yoon is biased closed and would *inherently* open due to a difference in pressure between the lumen and the ambient.” *11/14/06 Office Action*, pp. 2-3. The Examiner further stated that the “slit of Yoon is also configured to *inherently* allow the flaps to flex outward when the internal pressure exceeds the external pressure by a second amount.” *Id.*, p. 3. Initially, Appellants note that any structure, even those such as watertight bulkheads will *inherently* open when subjected to great enough fluid pressure. Yet, those skilled in the art would not consider that the bulkhead was designed to open “in response to a difference between a fluid pressure.” Rather, it is respectfully submitted, the opening of either the valve of Yoon or the watertight bulkhead due to a difference in fluid pressure represents a failure of the structure (*i.e.*, behavior directly contradicting the purpose for which it was designed). That is, the valve of Yoon is designed to prevent fluid flow despite any

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difference in fluid pressure to which it is likely to be exposed. As described above, even when the slit of Yoon is opened by the insertion of the trocar 36, thereinto, fluid flow is still prevented as the flaps of the Yoon device seal around the outside of the trocar 36. Thus, it is respectfully submitted that the Examiner mischaracterized the valve of Yoon as "configured" to allow the flaps to open due to a pressure differential. In fact, it is configured to precisely the opposite by remaining sealed at all times and at all pressure differentials to which it is expected to be exposed.

Furthermore, Appellants note that the Examiner withdrew the 35 U.S.C. § 102(b) rejection as anticipated by Yoon for claim 61. *11/14/06 Office Action*, p. 6. The Examiner agreed with the Appellants' argument that the device of Yoon does not allow flow from outside the catheter to the inside based on a pressure difference. *Id.* However, the Examiner maintained the rejection for claim 43 because the recitation of claim 43 is broader. Specifically, the Examiner appears to imply that the compound slit of claim 43 will "open out whether due to a force of a solid object or the force of a differential fluid pressure." *Id.* Therefore, the Examiner asserts that Yoon anticipates the compound slit of claim 43. However, this implication is misplaced since Yoon opens the valve flaps *only* due to a force of a solid object (*i.e.*, trocar 36) and never permits fluid flow therethrough while claim 43 of the present invention explicitly recites opening the compound slit due to "a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter."

Thus, it is respectfully submitted that Yoon does not disclose or suggest a

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compound slit "opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter," as recited in claim 43 and Appellants respectfully request that the Board overturn this rejection of claim 43 and claim 44 which depends directly therefrom.

II. The Rejection of Claims 43 - 44 and 61 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 3,303,847 to Eaton Should be Reversed.

A. The Examiner's Rejection

In the Final Office Action, claims 43 - 44 and 61 were rejected under 35 U.S.C. 102(b) as anticipated by Eaton. *11/14/06 Office Action*, p. 3.

Eaton describes a disposable container-applicator for liquids and fluid materials adapted to hold and dispense liquids or fluid materials into various openings of the human body. *Eaton*, col. 1, ll. 9-13. The container-applicator includes a "collapsible or squeezable tube" which opens only when the body portion 1 is physically deformed by a manual pressure applied thereto and which remains closed at all times when no manual pressure is applied. *Id.*, col. 3, ll. 65-70. Specifically, Eaton states that "pressure applied to the body portion 1 will cause the slits 8 and 9 of the flexible catheter to part slightly. *Id.* Eaton further states that, "when the container is not subjected to [manual] pressure, such [an] opening will remain closed sufficiently tightly to retain the contents of the container-applicator against the force of gravity." *Id.*, col. 3, l. 73 - col. 4, l. 1. This situation is the only one in which Eaton contemplates fluid pressure against the slits

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8 and 9 (*i.e.*, when the container-applicator is held with the opening facing downward) and the valve is designed to remain closed under these conditions.

B. Eaton Does Not Disclose a Compound Slit Opening in Response to a Difference Between a Fluid Pressure Within the Lumen and a Fluid Pressure Outside the Catheter as Recited in Claim 43.

Claim 43 has been recited above. In the final rejection, the Examiner stated that the "slit of Eaton is biased closed and opens due to [a] difference in pressure between the lumen and the ambient." *11/14/06 Office Action*, p. 3. The Examiner further stated that Appellants have misunderstood the Eaton reference and asserted that the valve of Eaton opens when the container is squeezed because this increases a fluid pressure within the container. *Id.*, p. 6.

However, it is respectfully submitted that Eaton includes no description or suggestion of the Examiner's assertion and, in fact, includes no mention of *fluid* pressure in any way influencing the state of the valve. Furthermore, Appellants submit that the direct statement in Eaton that the slits part slightly when the container is squeezed describes a mechanical deformation of the valve due to the squeezing and not any pressure activated valve behavior which is nowhere described and that any suggestion that this is a pressure activated valve is being read into the patent in hindsight by the Examiner. The mechanical deformation is evidenced from the description of the flexibility of the material from which the container-applicator is made. Specifically, due to the material, the opening remains closed to retain the contents of the container-applicator against gravity induced fluid pressure and opens slowly when manual

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pressure is applied to the body portion 1. Furthermore, Eaton nowhere implies that fluid pressure is used to part the slits since Eaton explicitly discloses a direct relationship between the material and the slits parting by reciting the "slight pressure applied to the body portion 1 will cause the slits or cuts 8 and 9 of the flexible catheter to part slightly." *Eaton*, col. 3, ll. 67-69. At no point does Eaton state or suggest that the manual pressure increases a fluid pressure which, in turn, forces the slits to part.

Thus, it is respectfully submitted that Eaton does not disclose or suggest a compound slit "opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter," as recited in claim 43 and Appellants respectfully request that the Board overturn this rejection of claim 43 and claims 44 and 61 which depend directly therefrom.

- C. Eaton Does Not Disclose the Flaps Flex into the Lumen to Allow Fluid Outside the Catheter to Enter the Lumen When the Fluid Pressure Outside the Catheter Exceeds the Fluid Pressure Within the Lumen by a Second Predetermined Amount as Recited in Claim 61.

Claim 61 recites a compound slit configured so that "when the fluid pressure outside the catheter exceeds the fluid pressure within the lumen by a second predetermined amount, the flaps flex into the lumen to allow fluid outside the catheter to enter the lumen." In the final rejection of claim 61, the Examiner stated that the "slit of Eaton is also configured to inherently allow the flaps to flex into the lumen based on a predetermined pressure difference

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between the ambient pressure and the pressure inside the lumen.” *11/14/06 Office Action*, p. 3.

However, as discussed above, the opening of Eaton is not based on a difference in fluid pressure and in any case no opening of the slits inward is disclosed in Eaton under any circumstances.

That is, similar to the slit of Yoon, any opening of the valve of Eaton by the slits flexing into the lumen represents a failure of the structure (*i.e.*, behavior directly contradicting the purpose for which it was designed). Because the slits of Eaton open only when manual pressure is applied to the body to mechanically deform the opening, the container-applicator is designed to only open in a predetermined direction. The only plausible way of the slit in Eaton to flex into the lumen is to forcibly “de-pressurize” (*e.g.*, increase the size of) the body 1. However, this is nowhere suggested and it is unclear whether the container of Eaton would survive such an operation or what purpose this would serve. That is, Eaton does not disclose the use of the container-applicator for fluid flow from the ambient into the lumen. In fact, Eaton shows that the container is filled through an open end 2 which is later sealed. *Eaton*, col. 3, ll. 22-28.

Thus, it is respectfully submitted therefore that Eaton does not disclose or suggest “a compound slit configured so that “when the fluid pressure outside the catheter exceeds the fluid pressure within the lumen by a second predetermined amount, the flaps flex into the lumen to allow fluid outside the catheter to enter the lumen,” as recited in claim 61 and Appellants respectfully request that the Board overturn this rejection of claim 61.

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III. The Rejection of Claims 43 - 44, 46 and 61 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 2,063,424 to Ferguson Should be Reversed.

A. The Examiner's Rejection

In the Final Office Action, claims 43 - 44, 46 and 61 were rejected under 35 U.S.C. 102(b) as anticipated by Ferguson. *11/14/06 Office Action*, p. 3. Ferguson discloses a nursing nipple with an orifice designed to automatically regulate a flow of food therefrom. *Ferguson*, p. 1, col. 1, ll. 1-4.

B. Ferguson Does Not Disclose an Elongate Catheter as Recited in Claim 43.

Claim 43 was recited above. In the final rejection, the Examiner stated that Ferguson discloses a catheter because the nursing nipple is a tubular device that is inserted into a body cavity (mouth) to inject fluids (milk). *11/14/06 Office Action*, p. 6. However, it is respectfully submitted that a catheter is a tubular device "designed for insertion into canals, vessels, passageways, or body cavities so as to permit injection or withdrawal of fluids or substances or to maintain the openness of a passageway." (Webster's Third International Dictionary, 1986). This definition is entirely consistent with the detailed description and figures of the present invention. In contrast, the nursing nipple for a baby's bottle shown in Ferguson is designed to be grasped between a baby's lips and is not suitable for the injection to or withdrawal of any substance from a body cavity. Injection is defined as driving or forcing fluid into a vessel,

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cavity or tissue. *Id.* The nursing nipple is simply a device like a straw which allows an infant to draw fluid from a container – fluids are not thrust into the infant's mouth but are drawn thereinto under the infant's direction.

Thus, it is respectfully submitted that Ferguson does not disclose or suggest "an elongate catheter," as recited in claim 43 and Appellants respectfully request that the Board overturn this rejection of claim 43 and claims 44, 46 and 61 which depend directly therefrom.

C. Ferguson Does Not Disclose a Compound Slit Opening in Response to a Difference Between a Fluid Pressure Within the Lumen and a Fluid Pressure Outside the Catheter as Recited in Claim 43.

Claim 43 has been recited above. In the final rejection, the Examiner stated that Ferguson discloses this recitation of claim 43. However, it is respectfully submitted that, similar to Eaton, the valve of Ferguson does not open in response to fluid pressure applied thereto. Rather, the valve of Ferguson is opened by the physical deformation of the nipple as it is squeezed in the mouth of the infant with the suction drawing the liquid through this opening. Specifically, Ferguson states that, during use:

the nipple is of course positioned between the jaws of infant; and obviously, closure of the infant's jaws will compress the nipple from above and below, with the result that the slots will gape in the manner illustrated in Figs. 4 and 5...It will be readily understood, that when the nipple is applied to a bottle containing liquid food; the normal jaw action of the infant in the act of nursing will regulate the size of the orifice and consequently the flow of food.

Ferguson, p. 1, col. 2, l. 49 - p. 2, col. 1, l. 17.

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The Examiner stated that the slit of Ferguson is biased closed and opens due to differences in pressure between the lumen and the ambient. *11/14/06 Office Action*, pp. 3-4. However, as illustrated by this quoted passage, it is respectfully submitted that the nipple of Ferguson opens only when mechanically compressed between the jaws of an infant and does not open due to a pressure differential. Although a pressure differential may be applied by an infant's sucking, the opening is only created (*i.e.*, the slits are parted from one another) only by the compression from the infant's jaws. *Id.*, p. 2, col. 1, ll. 20-23. In addition, Ferguson states that the improved nipple contains a perforation 6 and that "no amount of either compression or distortion can possibly close this vent 6." *Id.*, p. 2, col. 2, ll. 18-22, Fig. 7. Furthermore, the intersecting slots 3, 4, and 5 are never fully closed and "no amount of compression or distortion can possibly close the slots 3, 4, 5." *Id.*, p. 2, col. 2, ll. 63-65. Figs. 3-5 show a nipple for a baby bottle which is designed to open through the jaw action of an infant. The nipple of Ferguson is designed to exhibit substantially uniform behavior regardless of its rotational position within an infant's mouth. That is, the nipple of Ferguson opens in a substantially similar manner despite the orientation of slits therein to the direction of the compressive force from the jaws. Specifically, Ferguson states that, in any position one of the slots "will invariably be within 15 degrees of either vertical position, or horizontal position...and that such slight variations from the direction of compression, will not, to any appreciable extent affect the result of compression illustrated in Figs. 4 and 5." *Id.*, p. 1, col. 2, ll. 41-48. Therefore, it is clear that the opening of the slots shown in Figs. 4 and 5 is the result of the mechanical compression of the nipple from

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the jaws (*i.e.*, mechanical deformation) and not due to any fluid pressure differential applied thereto.

Thus, it is respectfully submitted that Ferguson does not disclose or suggest "a compound slit "opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter," as recited in claim 43 and Appellants respectfully request that the Board overturn this rejection of claim 43 and claims 44, 46, and 61 which depend directly therefrom.

IV. The Rejection of Claims 43 - 44 and 46 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 3,718,140 to Yamauchi Should be Reversed.

A. The Examiner's Rejection

In the Final Office Action, claims 43 - 44 and 46 were rejected under 35 U.S.C. 102(b) as being anticipated by Yamauchi. *11/14/06 Office Action*, p. 4. Yamauchi describes a nursing bottle nipple adapted for use with a nursing bottle assembly of the collapsible milk bag type. *Yamauchi*, abstract.

B. Yamauchi Does Not Disclose an Elongate Catheter as Recited in Claim 43.

Claim 43 was recited above. In the final rejection, the Examiner implied that Yamauchi discloses a catheter because the nursing nipple is a tubular device that is inserted into

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a body cavity (mouth) to inject fluids (milk). *11/14/06 Office Action*, p. 6. However, similar to the Ferguson reference, it is respectfully submitted that a catheter is a tubular device “designed for insertion into canals, vessels, passageways, or body cavities so as to permit injection or withdrawal of fluids or substances or to maintain the openness of a passageway.” (Webster’s Third International Dictionary, 1986). This definition is entirely consistent with the detailed description and figures of the present invention. In contrast, because Yamauchi also describes a nursing nipple, Appellants reiterate that the nursing nipple for a baby’s bottle shown in Yamauchi is designed to be grasped between a baby’s lips and controlled thereby and is not suitable for the injection of any substance to or withdrawal of any substance from a body cavity. Injection is defined as driving or forcing fluid into a vessel, cavity or tissue. *Id.* The nursing nipple is simply a device like a straw which allows an infant to draw fluid from a container.

Thus, it is respectfully submitted that Yamauchi does not disclose or suggest “an elongate catheter,” as recited in claim 43 and Appellants respectfully request that the Board overturn this rejection of claim 43 and claims 44 and 46 which depend directly therefrom.

C. Yamauchi Does Not Disclose a Compound Slit Opening in Response to a Difference Between a Fluid Pressure Within the Lumen and a Fluid Pressure Outside the Catheter as Recited in Claim 43.

Claim 43 has been recited above. In the final rejection, the Examiner stated that Yamauchi discloses this recitation of claim 43. However, it is respectfully submitted that,

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similar to Ferguson, the valve of Yamauchi does not open in response to fluid pressure applied thereto. Rather, the valve of Ferguson is opened by the physical deformation of the nipple as it is squeezed in the mouth of the infant with any suction applied drawing the liquid through this opening. It is respectfully submitted that the term "suction" as used in Yamauchi is used to describe the process by which an infant draws milk from a bottle or breast which is mechanical indeed. However, anyone who has milked a cow or seen that a cow can be milked by hand will realize that the milk is drawn from the breast by a squeezing, pulling action and that such "suction" involves no application of negative air pressure. If any suction is applied, it is to retain the breast in the mouth and has no effect on the drawing of liquid from the breast. The same is true of nipples for infant bottles as they are designed to operate in a manner resembling as closely as possible a natural breast. Therefore, Appellants submit that any reference utilizing a nursing nipple utilizes a mechanical deformation, not a fluid pressure differential, to open a valve for fluid flow and that the term suck or suction is simply an inaccurate colloquialism for the process by which an infant draws milk from a breast.

Thus, it is respectfully submitted that Yamauchi does not disclose or suggest "a compound slit "opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter," as recited in claim 43 and Appellants respectfully request that the Board overturn this rejection of claim 43 and claims 44 and 46 which depend directly therefrom.

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V. The Rejection of Claim 45 Under 35 U.S.C. § 103(a) as Obvious Over Eaton in View of U.S. Patent No. 5,798,018 to Engelson et al. Should be Reversed.

A. The Examiner's Rejection

In the Final Office Action, claim 45 was rejected under 35 U.S.C. 103(a) as obvious over Eaton in view of Engelson. *11/14/06 Office Action*, p. 5. The Examiner stated that Eaton discloses the invention substantially as claimed except for a collar disposed at the distal end of the catheter, but that Engelson discloses a collar used on a similar catheter. *Id.*

B. The References do not Disclose the Subject Matter Recited in Claim 45.

Claim 43 from which claim 45 depends has been recited above. Engelson purports to disclose a catheter used in cardiovascular and endovascular procedures to deliver diagnostic, therapeutic, or vaso-occlusive agents to a target site within a human body accessible by a system of natural passageways within that body. *Engelson*, Abstract. In its entirety, Engelson describes how the distal end of the catheter may reach the target site for injection of the agent, but includes no disclosure of a pressure differential opening a valve for the delivery.

Thus, because claim 45 depends from, and, therefore includes all of the elements recited in claim 43, it is respectfully submitted that neither Eaton nor Engelson, either alone or in combination, discloses or suggests the subject matter of claim 45. Accordingly, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of

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claim 45.

VI. The Rejection of Claim 45 Under 35 U.S.C. § 103(a) as Obvious Over Yoon in View of U.S. Patent No. 5,798,018 to Engelson et al. Should be Reversed.

A. The Examiner's Rejection

In the Final Office Action, claim 45 was rejected under 35 U.S.C. 103(a) as obvious over Yoon in view of Engelson. *11/14/06 Office Action*, p. 5. The Examiner stated that Yoon discloses the invention substantially as claimed except for a collar disposed at the distal end of the catheter, but that Engelson discloses a collar used on a similar catheter. *Id.*

B. The References do not Disclose the Subject Matter Recited in Claim 45.

Claim 43 from which claim 45 depends has been recited above. As discussed above with the combination of Eaton in view of Engelson, Engelson discloses a catheter used in cardiovascular and endovascular procedures to deliver diagnostic, therapeutic, or vaso-occlusive agents to a target site within a human body accessible by a system of natural passageways within that body. *Engelson*, Abstract. In its entirety, Engelson describes how the distal end of the catheter may reach the target site for injection of the agent, but includes no disclosure of a pressure differential opening a valve for the delivery.

Thus, because claim 45 depends from, and, therefore includes all of the elements

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recited in claim 43, it is respectfully submitted that neither Yoon nor Engelson, either alone or in combination, discloses or suggests the subject matter of claim 45. Accordingly, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 45.

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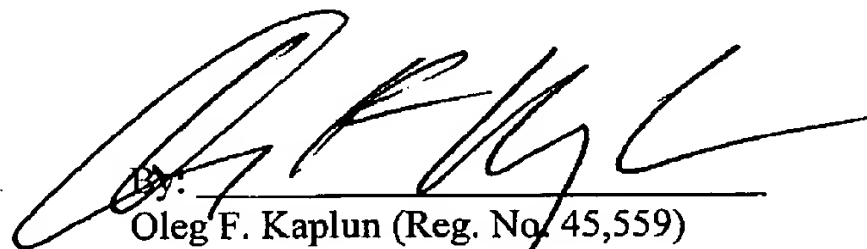
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8. Conclusions

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) and indicate that claims 43 - 46 and 61 are allowable.

Respectfully submitted,

Date: April 11, 2007


By: _____
Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcia, LLP
150 Broadway, Suite 702
New York, NY 10038
Tel: (212) 619-6000
Fax: (212) 619-0276

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CLAIMS APPENDIX

43. (Rejected) A medical device comprising:
- an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter; and
- a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.
44. (Rejected) A medical device according to claim 43, wherein the compound slit is disposed on a distal end of the elongate catheter.
45. (Rejected) A medical device according to claim 44, further comprising a collar disposed at the distal end of the catheter.
46. (Rejected) A medical device according to claim 43, wherein the compound slit is a tricuspid slit.
61. (Rejected) A medical device according to claim 43, wherein the compound slit is configured so that, when the fluid pressure within the lumen exceeds the fluid pressure outside the catheter by a first predetermined amount, flaps of the hemispherical portion formed by the compound slit flex outward away from a longitudinal axis of the catheter to allow fluid within the lumen to exit and when the fluid pressure outside the catheter exceeds the fluid pressure within the lumen by a second predetermined amount, the flaps flex into the lumen to allow fluid outside the catheter to enter the lumen.

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EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

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RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.